

REMARKS

Claims 1-3, 5-10, 13, 15-18, 20-23 and 32-38 are currently pending. Claims 1, 34, 36 and 37 are currently amended to recite a catheter or syringe, and support can be found, for example, in the specification at paragraph [0024]. Claim 1 is also amended to recite a blunt tip and support can be found, for example, in the specification at paragraph [0019]. Claims 13, 17, 18, 21, 22 are amended to correct the antecedent basis. Claims 4 and 24-31 were previously cancelled; and claims 11, 12, 14 and 19 are currently cancelled and incorporated into claim 1. The present claims are directed to a non-coring needle that minimizes or prevents damage to the site at which the needle is inserted and methods of use.

Interview Request

Applicants request an interview with the Examiner at his earliest convenience to discuss the patentability of the pending claims.

Claim Rejections – 35 USC 112, 1st paragraph

Claims 6-10 are rejected as allegedly failing to comply with the written description requirement. The Examiner states that there “is no teaching of a distal end with first and second extensions that are non-pointed, therefore this subject matter is drawn to figures 3-6.” Although Figures 3-6 are illustrated as having a pointed tip, the specification states in paragraph [0043] that “each of the disclosed aspects and embodiments of the present invention may be considered individually or in combination with other aspects, embodiments, and variations of the invention.” Since Figures 1, 2, 7 and 8 are shown as having a curvilinear blunt tip, as described in paragraph [0019], there is adequate written description for such a curvilinear tip being used in combination with the other aspects of Figures 3-6.

Claim Rejections – 35 USC 112, 2nd paragraph

Claims 1-3, 5-23 and 32 are rejected as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Examiner suggests that the term “dull” should be used rather than “non-pointed” in claim 1. In view of the Examiner’s suggestion, Applicants have amended claim 1 to recite

“blunt” rather than “non-pointed”, and support for this can be found in paragraph [0019] of the specification.

Claim Rejections – 35 USC 102

Claims 1, 2, 6-10 and 32-38 stand rejected under 35 U.S.C. 102(b) as being allegedly anticipated by US Patent No. 4,826,492 to Magasi (“Magasi”). However, Magasi does not describe a drug delivery device comprising a catheter or syringe and a needle attached to a distal portion, the needle having a distal-most end that is a curvilinear blunt tip. With reference to Figure 6, the Examiner states that the “first surface is indented toward to second surface,” however Figures 6 and 7 simply illustrate an intermediate stage in the method of manufacture and do not show the final product. Rather, Figures 1 and 2 show the end product and these figures clearly do not show a “curvilinear blunt tip”. Magasi describes tip 2 as a “puncturing tip” and it is illustrated in Figs. 1 and 2 as a sharp point. Additionally, the slanted surface of the tip results in a projected area of the openings 5 that is not smaller, but is actually larger than the cross-sectional area of a section of the shaft proximal to the distal end. Furthermore, it would go against the teaching of Magasi to create a drug delivery device by combining an intermediate product with a catheter or syringe. For at least these reasons, Applicants submit that Magasi does anticipate claims 1, 34, 36 or 37 (and all claims that depend therefrom) and Applicants request withdrawal of this rejection.

Claims 33-38 stand rejected under 35 U.S.C. 102(b) as being allegedly anticipated by US Patent No. 3,788,320 to Dye (“Dye”). However, Dye does not describe a needle having a distal opening or a distal-most end that is a curvilinear blunt tip. The face 40, face 42 and heel face 62 of stylet 22 inserted into needle 10 form a closed tip, thus there are *no openings* (column 2, lines 49-60). Therefore, there is also no projected area of the openings, as recited in claim 1. Additionally, as the Figures illustrate, tip 54 is pointed, and therefore Dye does not disclose a curvilinear blunt tip. Furthermore, the stylet is removably inserted into the needle to pierce the skin and then is removed for use of the needle, thus Dye does not disclose a drug delivery device comprising a catheter or syringe and a needle. For at least these reasons, Applicants submit that Dye does anticipate claims 33-38 and Applicants request withdrawal of this rejection.

Claim Rejections – 35 USC 103

Claims 3, 5 and 12 (which depend directly or indirectly from claim 1) stand rejected under 35 U.S.C. 103(a) as being allegedly rendered obvious over Magasi in view of US Patent No. 4,537,593 to Alchas (“Alchas”). As stated above, Magasi does not describe a needle having a distal-most end that is a curvilinear blunt tip. Alchas does not make up for this deficiency. The tip of Alchas is clearly the endpoint of two straight lines. Further, Alchas states that the closed planar portion 31 “terminates at a straight edge 32 lying at an angle to longitudinal axis 34” (see col. 5, lines 42-46). Further, Alchas states that “flat portion 31 includes a tapered portion 35 which is tapered toward straight edge 32 in a razor-like fashion” (see col. 5, lines 53-55). Therefore, Applicants submit that Alchas does not make up for the deficiencies of Magasi. For at least this reason, Applicants submit that claims 3, 5, and 12 are not rendered obvious by the combination of Alchas and Magasi, and Applicants request withdrawal of this rejection.

Claims 11 and 13-16 (which depend directly or indirectly from claim 1) stand rejected under 35 U.S.C. 103(a) as being allegedly rendered obvious over US Patent No. 6,346,099 to Altman (“Altman”). It is noted that the Examiner does not state that the claims are rejected over Magasi in view of Altman, however the Examiner’s discussion appears to indicate such. As stated above, Magasi does not describe a needle having a distal most end that is a curvilinear blunt tip. Altman does not make up for this deficiency. Specifically, Altman describes a “simple straight hollow 316 LVM stainless steel needle.” (See col. 5, lines 55-56; Fig. 3). For at least this reason, Applicants submit that claims 11 and 13-16 are not rendered obvious over Altman and Magasi, individually or together. As such, Applicants request withdrawal of this rejection.

Claims 17-20 (which depend directly or indirectly from claim 1) stand rejected as being allegedly rendered obvious over Magasi in view of US Patent No. 5,873,864 to Luther (“Luther”). As stated above, Magasi does not describe a needle having a distal most end that is a curvilinear blunt tip. Luther does not make up for this deficiency. For at least this reason, Applicants submit that claims 17-20 are not rendered obvious by the combination of Magasi and Luther. As such, Applicants request withdrawal of this rejection.

Claim 21 (which depends from claim 1) stands rejected under 35 U.S.C. 103(a) as being allegedly rendered obvious over Magasi in view of US Patent No. 5,843,048 to Gross (“Gross”). Applicants submit that there is no motivation to combine the teachings of Magasi and Gross. Specifically, Gross describes a “blunted tip” (40). One skilled in the art would not be motivated to modify the needle of Magasi to have a blunted tip because the design of the pointed tip is crucial to Magasi’s invention. The shape of the tip is meant to create “a reduced length of the incision line thus reducing the required pressure on the probe to puncture the patient’s skin.” (col 2, lines 13-18). A blunt curvilinear tip would increase the pressure necessary to puncture the skin and thus would go against the teaching of Magasi. For at least this reason, Applicants submit that there is no motivation to combine the teachings of Magasi with Gross and, as such, claim 21 is not rendered obvious by the combination of Magasi and Gross. Accordingly, Applicants request withdrawal of this rejection.

Claims 22 and 23 stand rejected as being allegedly rendered obvious over Magasi in view of US Patent No. 5,817,052 to Johnson (“Johnson”). As stated above, Magasi does not describe a needle having a distal most end that is a curvilinear blunt tip. Johnson does not make up for this deficiency. For at least this reason, Applicants submit that claim 21 is not rendered obvious by the combination of Magasi and Johnson. As such, Applicants request withdrawal of this rejection.

CONCLUSION

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees required in connection with the filing of this response, are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,
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